IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ARALEZ PHARMACEUTICALS INC.; ARALEZ PHARMACEUTICALS TRADING DAC; ARALEZ PHARMACEUTICALS US INC.; POZEN INC.	)	
Plaintiffs,	)	C.A. No. 2:17-cv-71
v.	)	
TEVA PHARMACEUTICALS USA, INC.; TEVA PHARMACEUTICAL INDUSTRIES LTD.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Aralez Pharmaceuticals Inc. ("API"), Aralez Pharmaceuticals Trading DAC ("Aralez Ireland"), Aralez Pharmaceuticals US Inc. ("Aralez US"), and Pozen Inc. ("Pozen") (collectively, "Aralez" or "Plaintiffs"), for their Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively "Teva" or "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff API is a public corporation organized and existing under the laws of British Columbia having its principal place of business at 7100 West Credit Avenue, Suite 101, Mississauga, Ontario L5N 0E4.

2. Plaintiff Aralez Ireland is a corporation organized and existing under the laws of Ireland having its principal place of business at 47-49 St. Stephen's Green, Dublin 2, Ireland.

3. Plaintiff Aralez US is a corporation organized and existing under the laws of Delaware having its principal place of business at 400 Alexander Park Drive, Princeton, NJ 08540.

4. Plaintiff Pozen is a corporation organized and existing under the laws of Delaware having its principal place of business at 8310 Bandford Way, Raleigh, NC 27615 and at c/o Aralez Pharmaceuticals US Inc., 400 Alexander Park Drive, Princeton, NJ 08540.

5. On information and belief, Defendant Teva USA is a corporation organized and existing under the laws of Delaware having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

6. On information and belief, Teva USA, by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of Texas and throughout the United States.

7. On information and belief, Defendant Teva Ltd. is a corporation organized and existing under the laws of Israel having its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

8. On information and belief, Teva Ltd., by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of Texas and throughout the United States.

9. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd.

10. On information and belief, Teva USA and Teva Ltd. are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic

drug products. On information and belief, the acts of Teva USA and Teva Ltd. complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

11. On information and belief, Teva USA and Teva Ltd. have cooperated and assisted in the preparation and filing of Teva's ANDA No. 209791 and will be involved in the manufacture, importation, marketing, and sale of the drug that is the subject of ANDA No. 209791 if it is approved.

NATURE OF THE ACTION

12. This is a civil action for the infringement of United States Patent Nos. 6,926,907 ("the '907 patent"), 8,206,741 ("the '741 patent"), 9,364,439 ("the '439 patent"), and 9,539,214 ("the '214 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from Teva USA's filing of an ANDA with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of the pharmaceutical product Yosprala® before the expiration of Plaintiffs' patents covering Yosprala® and its use.

JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

14. This Court has personal jurisdiction over Teva by virtue of the fact that, *inter alia*, Teva has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of Texas, and throughout the United States.

15. This Court also has personal jurisdiction over Teva because it has applied to the FDA for approval to engage in future activities, including the marketing of a generic version of

Yosprala® pursuant to ANDA No. 209791, that will be purposefully directed at the Eastern District of Texas.

16. Alternatively, assuming that the above facts do not establish personal jurisdiction over Teva Ltd., this Court may exercise jurisdiction over Teva Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Teva Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Teva Ltd. has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE YOSPRALA® NDA

18. Aralez Ireland is the holder of New Drug Application ("NDA") No. 205103 for Yosprala® (aspirin and omeprazole) delayed release tablets, 81 mg aspirin/40 mg omeprazole and 325 mg aspirin/40 mg omeprazole. The FDA approved NDA No. 205103 for Yosprala® on September 14, 2016 for the treatment of patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.

THE PATENTS-IN-SUIT

19. On August 9, 2005, the '907 patent, entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued to Pozen. A true and correct copy of the '907 patent is attached hereto as Exhibit A.

20. On June 26, 2012, the ’741 patent, entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs,” was duly and legally issued to Pozen. A true and correct copy of the ’741 patent is attached hereto as Exhibit B.

21. On June 14, 2016, the ’439 patent, entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs,” was duly and legally issued to Pozen. A true and correct copy of the ’439 patent is attached hereto as Exhibit C.

22. On January 10, 2017, the ’214 patent, entitled “Compositions and Methods for Delivery of Omeprazole Plus Acetylsalicylic Acid,” was duly and legally issued to Pozen. A true and correct copy of the ’214 patent is attached hereto as Exhibit D.

23. Pozen is the owner of the ’907, ’741, ’439, and ’214 patents. Pozen licensed the ’907, ’741, ’439, and ’214 patents to Aralez Ireland. Pozen, Aralez Ireland, and Aralez US are indirect wholly owned subsidiaries of API.

24. The ’907, ’741, and ’439 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the “Orange Book”) for both Yosprala® 81 mg aspirin/40 mg omeprazole and 325 mg aspirin/40 mg omeprazole tablets.

25. Plaintiffs anticipate that the ’214 patent will be listed in the Orange Book for both Yosprala® 81 mg aspirin/40 mg omeprazole and 325 mg aspirin/40 mg omeprazole tablets.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

26. On information and belief, Teva submitted ANDA No. 209791 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, and sale of Aspirin Delayed-release and Omeprazole Tablets, 81 mg/40 mg and 325 mg/40 mg (“Teva’s Generic Product”) as a generic version of Yosprala® 81 mg aspirin/40 mg omeprazole and 325 mg aspirin/40 mg omeprazole tablets.

27. By a letter dated December 9, 2016 (the "Teva Notice Letter"), Teva advised Aralez that it had submitted ANDA No. 209791 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of Teva's Generic Product prior to the expiration of the '907, '741, and '439 patents.

28. On information and belief, based upon, *inter alia*, the Teva Notice Letter, Teva is also seeking FDA approval to engage in the commercial manufacture, use, or sale of Teva's Generic Product before the expiration of the '214 patent.

29. Although as of the filing of this Complaint Plaintiffs have not yet received a certification under 21 U.S.C. § 355(j)(2)(B) with respect to the '214 patent, Plaintiffs anticipate that Teva will make noninfringement and invalidity arguments with respect to the '214 patent similar to those set forth in the Teva Notice Letter.

30. By submitting ANDA No. 209791, Teva has necessarily represented to the FDA that, upon approval, Teva's Generic Product will have the same active ingredients, method of administration, dosage form, and strength as Yosprala®, and will be bioequivalent to Yosprala®.

31. On information and belief, ANDA No. 209791 seeks FDA approval of Teva's Generic Product to be indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.

32. On information and belief, ANDA No. 209791 seeks FDA approval of Teva's Generic Product wherein the aspirin component will be indicated for:

- reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli,
- reducing the combined risk of death and nonfatal myocardial infarction in patients with a previous MI or unstable angina pectoris,

- reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris,
- use in patients who have undergone revascularization procedures when there is a pre-existing condition for which aspirin is already indicated.

33. On information and belief, ANDA No. 209791 seeks FDA approval of Teva's Generic Product wherein the omeprazole component will be indicated for decreasing the risk of developing aspirin associated gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers.

34. On information and belief, Teva will direct or control the treatment of patients using Teva's Generic Product with methods claimed in the '741,'439, and '214 patents, after the FDA approves ANDA No. 209791. On information and belief, this will occur at Teva's active behest and with its intent, knowledge and encouragement. On information and belief, Teva will actively encourage, aid and abet this treatment with knowledge that it is in contravention of Plaintiffs' rights under the '741,'439, and '214 patents.

35. On information and belief, Teva will knowingly provide Teva's Generic Product with instructions for use that substantially copy the instructions for Yosprala®, including instructions for treating patients using methods claimed in the '741,'439, and '214 patents.

36. On information and belief, Teva knows the instructions that will accompany Teva's Generic Product will induce and/or contribute to others using Teva's Generic Product in the manner set forth in the instructions.

37. On information and belief, physicians, health care providers, and/or patients will directly infringe one or more claims of the '741,'439, and '214 patents by using Teva's Generic Product in accordance with the instructions provided by Teva, after the FDA approves ANDA No. 209791.

38. On information and belief, Teva specifically intends that physicians, health care providers, and/or patients will use Teva's Generic Product in accordance with the instructions provided by Teva to directly infringe one or more claims of the '741,'439, and '214 patents. Teva therefore will actively induce and/or contribute to infringement of the '741,'439, and '214 patents.

39. On information and belief, Teva knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using Teva's Generic Product in a manner that directly infringes at least one claim of the '741,'439, and '214 patents.

40. On information and belief, Teva designed Teva's Generic Product for use in a way that would infringe the '741,'439, and '214 patents and will instruct users of Teva's Generic Product to use Teva's Generic Product in a way that would infringe the '741,'439, and '214 patents.

41. The Teva Notice Letter advised Aralez that Teva's ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Teva's opinion, the claims of the '907, '741, and '439 patents are invalid, unenforceable, and/or not infringed.

42. The Teva Notice Letter does not allege non-infringement of certain claims of the '907, '741, and '439 patents.

43. By not identifying non-infringement defenses for certain claims of the '907, '741, and '439 patents in the Teva Notice Letter, Teva admits Teva's Generic Product meets all limitations of those claims.

44. The Teva Notice Letter does not allege invalidity of certain claims of the '907 and '741 patents.

45. By not identifying invalidity defenses for certain claims of the ’907 and ’741 patents in the Teva Notice Letter, Teva admits the claims of the ’907 and ’741 patents for which invalidity defenses have not been raised are valid.

46. The Teva Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or § 112, or unenforceability of any claim of the ’907, ’741, and ’439 patents.

47. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or § 112, or unenforceability defenses for any of the ’907, ’741, and ’439 patents in the Teva Notice Letter, Teva admits the claims of those patents are valid under 35 U.S.C. §§ 101, 102 and § 112, and are enforceable.

48. On information and belief, Teva has made and will continue to make substantial and meaningful preparations in the United States to manufacture, sell, offer to sell, and/or import Teva’s Generic Product prior to the expiration of the ’907, ’741, ’439, and ’214 patents.

49. On information and belief, Teva’s preparations include, but are not limited to, the development of Teva’s Generic Product and the filing of ANDA No. 209791. These preparations indicate a refusal to change its course of action in the face of acts by Plaintiffs.

50. On information and belief, Teva continues to seek approval of ANDA No. 209791. On information and belief, upon approval by the FDA, Teva intends to immediately engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva’s Generic Product, infringing the ’907, ’741, ’439, and ’214 patents prior to their expiration.

51. There is an actual, real, immediate, and justiciable controversy between Aralez and Teva regarding the infringement, validity, and enforceability of the ’907, ’741, ’439, and ’214 patents.

52. Plaintiffs are commencing this action within 45 days of receiving the Teva Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I

INFRINGEMENT OF THE '907 PATENT

53. Plaintiffs incorporate each of the preceding paragraphs 1-52 as if fully set forth herein.

54. Teva submitted ANDA No. 209791 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product throughout the United States, including the Eastern District of Texas, prior to expiration of the '907 patent. By submitting the application, Teva committed an act of infringement of the '907 patent under 35 U.S.C. § 271(e)(2)(A).

55. The '907 patent claims, *inter alia*, and among other limitations, pharmaceutical compositions comprising an acid inhibitor and an NSAID.

56. On information and belief, Teva's Generic Product, if approved by the FDA, will consist of a pharmaceutical composition patented in the '907 patent.

57. On information and belief, Teva's manufacture, use, sale, offer for sale, and/or importation into the United States of Teva's Generic Product prior to the expiration of the '907 patent, including any applicable exclusivities or extensions, will infringe the '907 patent under 35 U.S.C. § 271(a). Teva will infringe one or more of the claims of the '907 patent.

58. On information and belief, Teva's Generic Product will infringe at least Claim 1 of the '907 patent which recites: "A pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising:

> (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;

(b) a non-steroidal anti-inflammatory drug (NSAID) in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms;

and wherein the unit dosage form provides for coordinated release such that:

(i) said NSAID is surrounded by a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher;

(ii) at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5."

59. On information and belief, Teva's Generic Product is a pharmaceutical composition containing omeprazole (an acid inhibitor) and aspirin (an NSAID) that will meet each of the limitations recited in paragraph 58 and therefore infringe Claim 1 of the '907 patent.

60. On information and belief, Teva was aware of the existence of the '907 patent and its listing in the Orange Book as demonstrated by Teva's reference to the '907 patent in the Teva Notice Letter.

61. On information and belief, Teva knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry will infringe one or more claims of the '907 patent.

62. On information and belief, Teva's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '907 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

63. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT II

INFRINGEMENT OF THE '741 PATENT

64. Plaintiffs incorporate each of the preceding paragraphs 1-52 as if fully set forth herein.

65. Teva submitted ANDA No. 209791 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product throughout the United States, including the Eastern District of Texas, prior to expiration of the '741 patent. By submitting the application, Teva committed an act of infringement of the '741 patent under 35 U.S.C. § 271(e)(2)(A).

66. On information and belief, Teva's manufacture, use, sale, offer for sale, and/or importation into the United States of Teva's Generic Product prior to the expiration of the '741 patent, including any applicable exclusivities or extensions, will infringe the '741 patent under 35 U.S.C. § 271(a), (b), and/or (c). Teva will infringe one or more of the claims of the '741 patent.

67. The '741 patent claims, *inter alia*, and among other limitations, pharmaceutical compositions comprising a proton pump inhibitor and aspirin.

68. On information and belief, Teva's Generic Product, if approved by the FDA, will consist of a pharmaceutical composition patented in the '741 patent.

69. On information and belief, Teva's Generic Product will infringe at least Claim 1 of the '741 patent which recites: "A pharmaceutical composition in unit dosage form comprising therapeutically effective amounts of:

> (a) a proton pump inhibitor selected from the group consisting of omeprazole, esomeprazole, lansoprazole, pantoprazole and rabeprazole, wherein at least a portion of said proton pump inhibitor is not surrounded by an enteric coating; and
>
> (b) aspirin, wherein said aspirin is surrounded by a coating that inhibits its release from

said dosage form unless said dosage form is in a medium with a pH of 3.5 or higher; wherein the unit dosage form provides for release of said proton pump inhibitor and said aspirin such that:

(i) upon introduction of said unit dosage form into a medium, at least a portion of said proton pump inhibitor is released regardless of the pH of the medium; and

(ii) said aspirin is released when the pH of said medium is 3.5 or higher."

70. On information and belief, Teva's Generic Product is a pharmaceutical composition containing omeprazole (a proton pump inhibitor) and aspirin that will meet each of the limitations recited in paragraph 69 and therefore infringe Claim 1 of the '741 patent.

71. On information and belief, Teva was aware of the existence of the '741 patent and its listing in the Orange Book as demonstrated by Teva's reference to the '741 patent in the Teva Notice Letter.

72. On information and belief, Teva knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry will infringe one or more claims of the '741 patent.

73. The '741 patent also claims, *inter alia*, methods wherein pharmaceutical compositions containing a proton pump inhibitor and aspirin are administered to reduce the risk of stroke or heart attack.

74. The use of Teva's Generic Product by physicians, health care providers and/or patients prior to patent expiry will directly infringe one or more claims of the '741 patent.

75. Teva will direct, control, encourage, aid and/or abet the direct infringement of one or more claims of the '741 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry.

76. On information and belief, Teva knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry will actively induce direct infringement of one or more claims of the '741 patent.

77. Teva's acts described in paragraphs 75-76 will be performed with knowledge of the '741 patent and with intent to encourage infringement prior to patent expiry.

78. On information and belief, Teva knows or should know that Teva's Generic Product will be especially made or especially adapted for use in an infringement of the '741 patent, and it is not a staple article or commodity of commerce suitable for substantial non-infringing use.

79. On information and belief, Teva knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '741 patent.

80. Teva's acts described in paragraphs 78-79 will be performed with knowledge of the '741 patent and with intent to encourage infringement prior to patent expiry.

81. On information and belief, Teva's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '741 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

82. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT III

INFRINGEMENT OF THE '439 PATENT

83. Plaintiffs incorporate each of the preceding paragraphs 1-52 as if fully set forth herein.

84. Teva submitted ANDA No. 209791 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product throughout the United States, including the Eastern District of Texas, prior to expiration of the '439 patent. By submitting the application, Teva committed an act of infringement of the '439 patent under 35 U.S.C. § 271(e)(2)(A).

85. On information and belief, Teva's manufacture, use, sale, offer for sale, and/or importation into the United States of Teva's Generic Product prior to the expiration of the '439 patent, including any applicable exclusivities or extensions, will infringe the '439 patent under 35 U.S.C. § 271(a), (b), and/or (c). Teva will infringe one or more of the claims of the '439 patent.

86. The '439 patent claims, *inter alia*, and among other limitations, pharmaceutical compositions comprising omeprazole and aspirin.

87. On information and belief, Teva's Generic Product, if approved by the FDA, will consist of a pharmaceutical composition patented in the '439 patent.

88. On information and belief, Teva's Generic Product will infringe at least Claim 1 of the '439 patent which recites: "A pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising therapeutically effective amounts of:

> (a) omeprazole, wherein at least a portion of the omeprazole is not surrounded by an enteric coating; and
>
> (b) aspirin surrounded by a coating that inhibits its release from the unit dosage form unless the unit dosage form is in a medium with a pH of 3.5 or higher;

wherein the unit dosage form provides for release of omeprazole such that upon introduction of

the unit dosage form into a medium, at least a portion of the omeprazole is released regardless of the pH of the medium."

89. On information and belief, Teva's Generic Product is a pharmaceutical composition containing omeprazole and aspirin that will meet each of the limitations recited in paragraph 88 and therefore infringe Claim 1 of the '439 patent.

90. On information and belief, Teva was aware of the existence of the '439 patent and its listing in the Orange Book as demonstrated by Teva's reference to the '439 patent in the Teva Notice Letter.

91. On information and belief, Teva knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry will infringe one or more claims of the '439 patent.

92. The '439 patent also claims, *inter alia*, methods wherein pharmaceutical compositions containing omeprazole and aspirin are administered to (i) reduce the risk of stroke or heart attack and (ii) reduce the incidence of NSAID-associated gastric ulcers in patients who are at risk of developing such ulcers.

93. The use of Teva's Generic Product by physicians, health care providers and/or patients prior to patent expiry will directly infringe one or more claims of the '439 patent.

94. Teva will direct, control, encourage, aid and/or abet the direct infringement of one or more claims of the '439 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry.

95. On information and belief, Teva knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry will actively induce direct infringement of one or more claims of the '439 patent.

96. Teva's acts described in paragraphs 94-95 will be performed with knowledge of the '439 patent and with intent to encourage infringement prior to patent expiry.

97. On information and belief, Teva knows or should know that Teva's Generic Product will be especially made or especially adapted for use in an infringement of the '439 patent, and it is not a staple article or commodity of commerce suitable for substantial non-infringing use.

98. On information and belief, Teva knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '439 patent.

99. Teva's acts described in paragraphs 97-98 will be performed with knowledge of the '439 patent and with intent to encourage infringement prior to patent expiry.

100. On information and belief, Teva's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '439 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

101. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV

INFRINGEMENT OF THE '214 PATENT

102. Plaintiffs incorporate each of the preceding paragraphs 1-52 as if fully set forth herein.

103. Teva submitted ANDA No. 209791 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale,

and/or importation of Teva's Generic Product throughout the United States, including the Eastern District of Texas, prior to expiration of the '214 patent. By submitting the application, Teva committed an act of infringement of the '214 patent under 35 U.S.C. § 271(e)(2)(A).

104. On information and belief, Teva's manufacture, use, sale, offer for sale, and/or importation into the United States of Teva's Generic Product prior to the expiration of the '214 patent, including any applicable exclusivities or extensions, will infringe the '214 patent under 35 U.S.C. § 271(b) and/or (c). Teva will infringe one or more of the claims of the '214 patent.

105. Any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '214 patent.

106. The '214 patent claims methods wherein pharmaceutical compositions containing omeprazole and aspirin are administered to patients in need thereof.

107. The use of Teva's Generic Product by physicians, health care providers and/or patients prior to patent expiry will directly infringe one or more claims of the '214 patent.

108. Teva will direct, control, encourage, aid and/or abet the direct infringement of one or more claims of the '214 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry.

109. On information and belief, Teva knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry will actively induce direct infringement of one or more claims of the '214 patent.

110. Teva's acts described in paragraphs 108-109 will be performed with knowledge of the '214 patent and with intent to encourage infringement prior to patent expiry.

111. On information and belief, Teva knows or should know that Teva's Generic Product will be especially made or especially adapted for use in an infringement of the '214 patent, and it is not a staple article or commodity of commerce suitable for substantial non-infringing use.

112. On information and belief, Teva knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '214 patent.

113. Teva's acts described in paragraphs 111-112 will be performed with knowledge of the '214 patent and with intent to encourage infringement prior to patent expiry.

114. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Teva has infringed one or more claims of the '907, '741, '439, and '214 patents by submitting ANDA No. 209791 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Product before the expiration of the '907, '741, '439, and '214 patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Teva's commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Teva's Generic Product will infringe one or more claims of the '907, '741, '439, and '214 patents under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Teva, its officers, agents, servants, and employees, and those persons in active

concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Teva's Generic Product prior to the expiration dates of the '907, '741, '439, and '214 patents, inclusive of any extensions;

D. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 209791 shall be a date that is not earlier than the expiration dates of the '907, '741, '439, and '214 patents, inclusive of any extensions;

E. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorney fees;

F. An award of costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

/s/ Dominick A. Conde by permission Wesley Hill

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